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Appeals Court Rules FDA 'Exceeded Its Authority' by Advising Public Against Use of Ivermectin to Treat COVID

The 5th Circuit U.S. Court of Appeals on Sept. 1 ruled the U.S. Food and Drug Administration exceeded its authority under federal law when it advised the public against using ivermectin.

By **Michael Nevradakis, Ph.D.**

64

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A federal appeals court last week overturned the dismissal of a lawsuit against the U.S. Food and Drug Administration (FDA), ruling that the agency exceeded its authority under federal law when it advised the public against using ivermectin.

Three doctors — Robert Apter, Mary Talley Bowden and Paul E. Marik, co-founder of the Front Line Critical Care Alliance (FLCCC) — in June 2022 sued the FDA, the U.S. Department of Health and Human Services (HHS), FDA Commissioner Robert Califf and HHS Secretary Xavier Becerra in the U.S. District Court for the Southern District of Texas.

The doctors alleged the FDA's guidance on ivermectin interfered with the doctor-patient relationship and their ability to prescribe an approved medication.

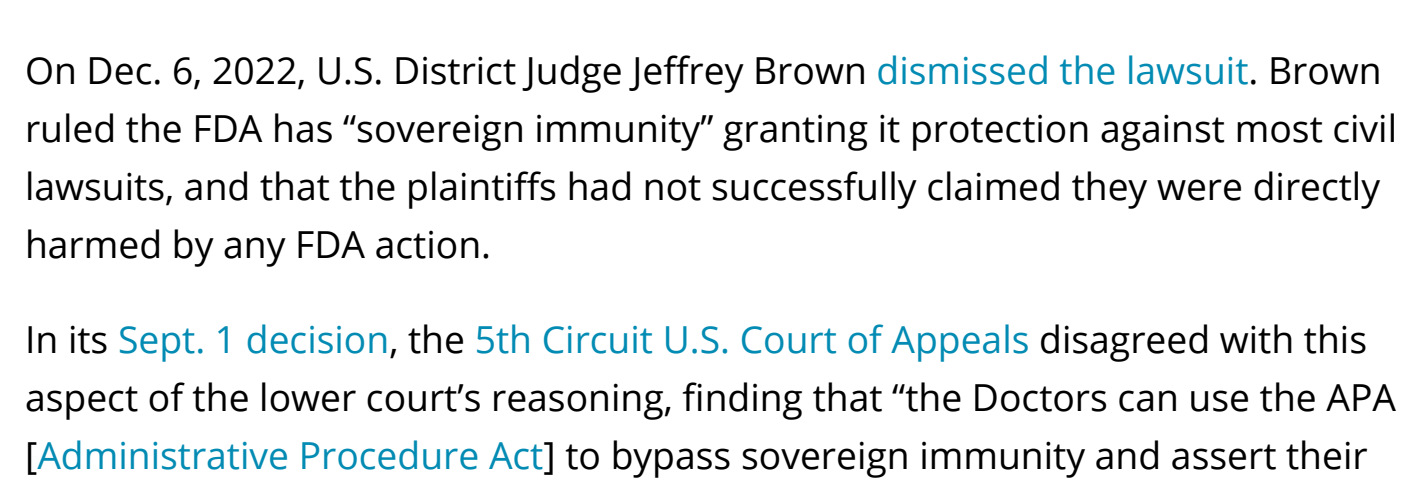
They also said their careers and professional reputations were harmed, as they faced sanctions from their employers, including suspensions and loss of privileges.

"Attempts by the FDA to influence or intervene in the doctor-patient relationship amount to interference with the practice of medicine, the regulation of which is — and always has been — reserved to states," the complaint stated.

The lawsuit also noted that the FDA approved ivermectin in 1996 for the treatment of a variety of diseases.

On Dec. 6, 2022, U.S. District Judge Jeffrey Brown dismissed the lawsuit. Brown ruled the FDA has "sovereign immunity" granting it protection against most civil lawsuits, and that the plaintiffs had not successfully claimed they were directly harmed by any FDA action.

In its Sept. 1 decision, the 5th Circuit U.S. Court of Appeals disagreed with this aspect of the lower court's reasoning, finding that "the Doctors can use the APA [Administrative Procedure Act] to bypass sovereign immunity and assert their ultra vires claims against the Agencies and the Officials."



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Ultra vires claims describe "actions taken by government bodies or corporations that exceed the scope of power given to them by laws or corporate charters."

Ray Flores, senior counsel for Children's Health Defense (CHD), told The Defender, "One of the three issues raised in the appeal was sufficient to overturn the District Court's dismissal of the case."

U.S. Circuit Judge Don Willett, writing for the three-judge panel, said, "FDA can inform, but it has identified no authority allowing it to recommend consumers 'stop' taking medicine."

Referring to a series of social media posts and public pronouncements by the FDA against the use of ivermectin for the treatment of COVID-19, Willett said, "FDA is not a physician. It has authority to inform, announce, and apprise — but not to endorse, denounce, or advise."

"The Doctors have plausibly alleged that FDA's [social media] Posts fell on the wrong side of the line between telling about and telling to," he added. "FDA argues that the Twitter posts are 'informational statements' that cannot qualify as rules because they 'do not "direct" consumers, or anyone else, to do or refrain from doing anything.' We are not convinced."

Kim Mack Rosenberg, acting general counsel for CHD, told The Defender, "This is an important decision and opens the door for doctors to vindicate important rights."

She added:

> "Damages alone cannot undo the harms the FDA caused with its notices. But legal recognition of the FDA's role is critical, and these plaintiffs now have a chance to present their standing arguments to the District Court and hopefully further litigate these critical issues which should not be allowed to go unaddressed."

Bowden lauded the ruling. "The FDA misled the public into thinking it has more authority than it does," she said. "This decision confirms that the FDA is not your doctor and has no authority to tell doctors how to practice medicine."

Other legal experts who spoke with The Defender also welcomed the ruling.

Attorney Todd Richardson, who represents Dr. Richard Eggleston, a retired Washington doctor facing the loss of his license over his public statements in favor of ivermectin, said that while "the administrative state is powerful and dangerous, this ruling trims it back and gives those fighting for the freedom of the people a little breath."

However, attorney Rick Jaffe, who also represents Eggleston in the same case, warned that since state medical boards and private employers — not the FDA — ultimately are the entities that can launch disciplinary proceedings against doctors, the ruling is "a little more complicated and nuanced" than it may appear at first glance.

"The long and short of it is that state medical boards, not the FDA, regulate the practice of medicine," Jaffe said. "They decide if the use of ivermectin and other off-label drug use aligns with the standard of care."

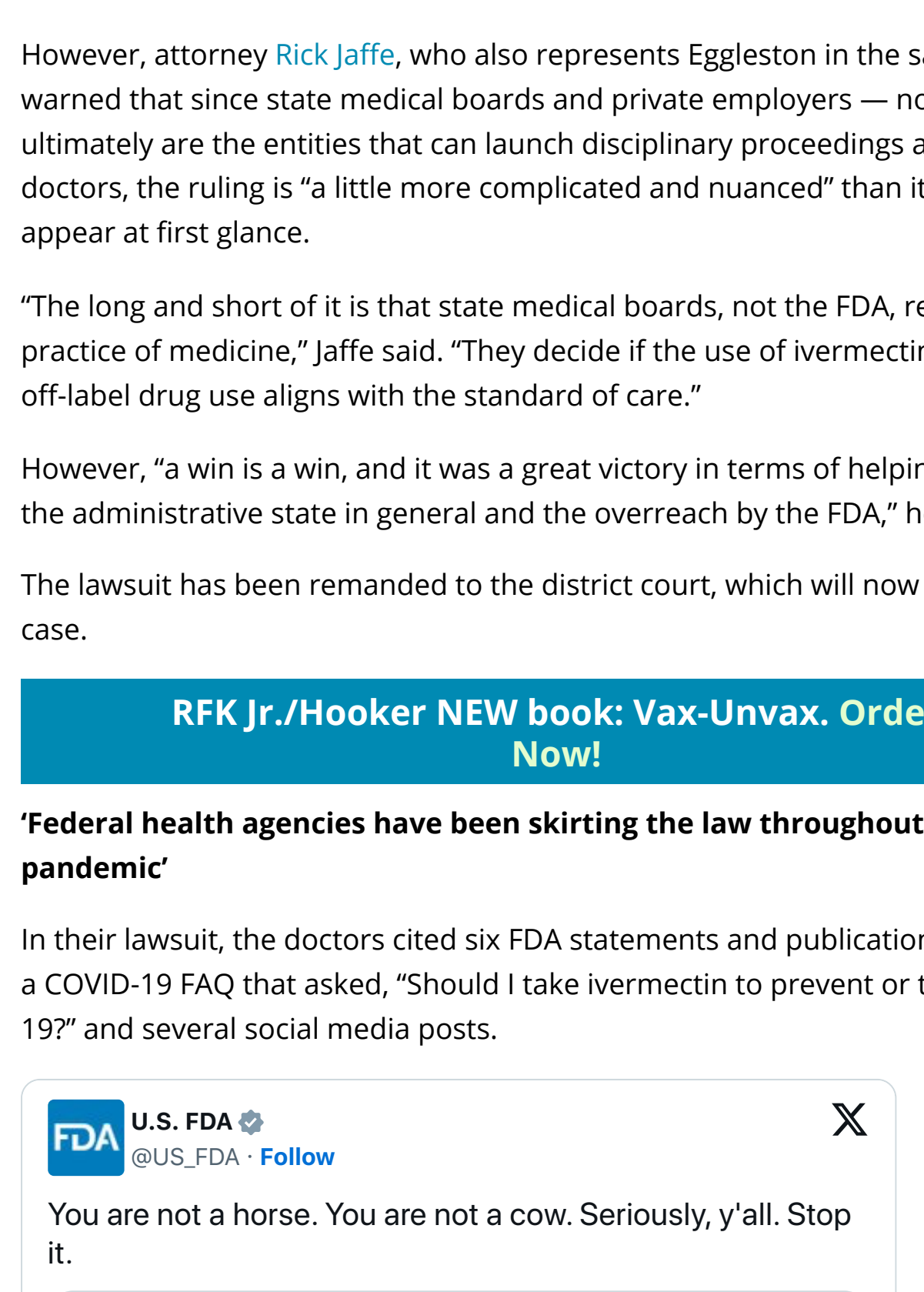
However, "a win is a win, and it was a great victory in terms of helping roll back the administrative state in general and the overreach by the FDA," he added.

The lawsuit has been remanded to the district court, which will now hear the case.

RFK Jr./Hooker NEW book: Vax-Unvax. Order Now!

'Federal health agencies have been skirting the law throughout the pandemic'

In their lawsuit, the doctors cited six FDA statements and publications including a COVID-19 FAQ that asked, "Should I take ivermectin to prevent or treat COVID-19?" and several social media posts.



U.S. FDA
@US_FDA · Follow

You are not a horse. You are not a cow. Seriously, y'all. Stop it.

fda.gov
Why You Should Not Use Ivermectin to Treat or Prevent COVID-19
Using the Drug ivermectin to treat COVID-19 can be dangerous and even lethal. The FDA has not approved the drug for that purpose.

4:57 AM · Aug 21, 2021

108.2K Reply Share

Read 15.5K replies

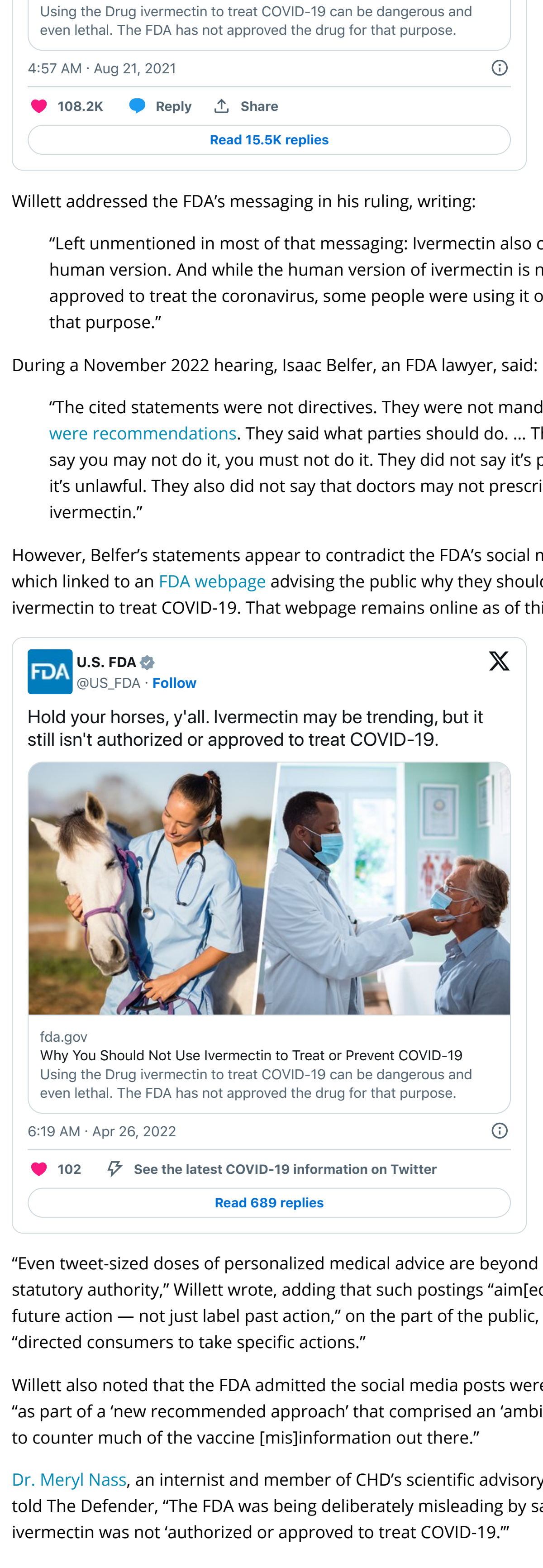
Willett addressed the FDA's messaging in his ruling, writing:

> "Left unmentioned in most of that messaging: Ivermectin also comes in a human version. And while the human version of ivermectin is not FDA-approved to treat the coronavirus, some people were using it off-label for that purpose."

During a November 2022 hearing, Isaac Belfer, an FDA lawyer, said:

> "The cited statements were not directives. They were not mandatory. They were recommendations. They said what parties should do. … They did not say you may not do it, you must not do it. They did not say it's prohibited or it's unlawful. They also did not say that doctors may not prescribe ivermectin."

However, Belfer's statements appear to contradict the FDA's social media posts, which linked to an FDA webpage advising the public why they should not use ivermectin to treat COVID-19. That webpage remains online as of this writing.



U.S. FDA
@US_FDA · Follow

Hold your horses, y'all. Ivermectin may be trending, but it still isn't authorized or approved to treat COVID-19.

fda.gov
Why You Should Not Use Ivermectin to Treat or Prevent COVID-19
Using the Drug ivermectin to treat COVID-19 can be dangerous and even lethal. The FDA has not approved the drug for that purpose.

6:19 AM · Apr 26, 2022

102 See the latest COVID-19 information on Twitter

Read 689 replies

"Even tweet-sized doses of personalized medical advice are beyond FDA's statutory authority," Willett wrote, adding that such postings "aim[ed] to curb future action — not just label past action," on the part of the public, and "directed consumers to take specific actions."

Willett also noted that the FDA admitted the social media posts were published "as part of a 'new recommended approach' that comprised an 'ambitio[us] effort to counter much of the vaccine [mis]information out there.'"

Dr. Meryl Nass, an internist and member of CHD's scientific advisory committee, told The Defender, "The FDA was being deliberately misleading by saying ivermectin was not 'authorized or approved to treat COVID-19.'"

"The FDA knew a licensed drug does not need to be authorized or approved for its uses," Nass said, referring to the off-label use of ivermectin for treating COVID-19. "The federal health agencies have been skirting the law throughout the pandemic."

In January 2022, the Maine Board of Licensure in Medicine suspended Nass for prescribing medications such as ivermectin and hydroxychloroquine to patients and has faced hearings resulting from this suspension. Last month, Nass sued the board, alleging it violated her First Amendment rights.

In a blog post, Jaffe wrote that the FDA's acknowledgment that doctors can legally prescribe ivermectin "has ZERO RELEVANCE in determining if a doctor can be prosecuted and sanctioned by a state medical board for prescribing these drugs for Covid."

"Big picture wise, it's a matter of federalism, i.e., the division of responsibilities between the federal and state governments. And the law is very clear here on who calls the shots," he wrote.

"[The 5th Circuit ruling] could help cases of public speech COVID misinformation, to the extent that medical boards cite in part rely on the FDA's position statement," Jaffe said. "However, it is just one part of the off-label battle. The real battle is going to be against the medical boards in standard of care cases."

Flores noted that while the FDA cannot directly take disciplinary actions or levy sanctions against doctors, its advice carries significant weight with federal, state and local officials, state medical boards and private employers. He said:

> "This is the trickle-down, cat and mouse game. Federal agencies recommend … but don't issue an edict or mandate."
>
> "Then, other officials in federal, state and local governments use these recommendations as an excuse for mandates, disciplinary actions, censorship and school requirements … With the FDA making such pronouncements, it is easy for disciplinary bodies to threaten doctors based on FDA recommendations."
>
> "This time, the FDA was caught in its own game."

Order Now 'The Wuhan Cover-up' by RFK Jr.!

FDA admits doctors have the authority to prescribe ivermectin to treat COVID

During oral arguments before the 5th Circuit on Aug. 8, Ashley Cheung Honold, a U.S. Department of Justice lawyer representing the FDA, said the "FDA explicitly recognizes that doctors do have the authority to prescribe ivermectin to treat COVID."

"FDA made these statements in response to multiple reports of consumers being hospitalized, after self-medicating with ivermectin intended for horses, which is available for purchase over the counter without the need for prescription," she added.

However, Bowden told The Epoch Times that many pharmacists still refuse to fill ivermectin prescriptions. She said:

> "This needs to come to an end. In telling my patients what medicines they can and cannot have access to, we effectively have a large group of pharmacists practicing medicine without a license. …"
>
> "They have no accountability for this, yet they are allowed to dictate patient care. I see it every single day. Enough is enough."

In late 2021, Houston Methodist Hospital suspended Bowden and launched an investigation into her use of ivermectin to treat COVID-19 patients and for sharing her views about ivermectin on social media. She ultimately resigned.

Marik faced similar disciplinary action. In November 2021, Sentara Norfolk General Hospital suspended him after he sued the hospital for banning his treatment protocol, which included the use of ivermectin.

Apter was referred to the Washington Medical Commission and the Arizona Medical Board for disciplinary proceedings related to prescribing ivermectin to patients for the treatment of COVID-19.

As of this writing, Tennessee is the only state in the U.S. where ivermectin can be purchased without a prescription, after the passage of Senate Bill 2188 in April 2022.

Ivermectin was developed in the 1970s as a veterinary medicine to treat parasitic diseases in livestock. But a decade or so later it was hailed as a "wonder drug" and received approval for human use as a therapeutic against diseases such as river blindness — or onchocerciasis — and lymphatic filariasis.

A collection of 99 studies examining the efficacy of ivermectin in treating COVID-19 has shown an overall 62% improvement in patients. And a study published Aug. 8 in Cureus found that ivermectin reduces excess deaths by up to 74%.

William C. Campbell, Ph.D., a microbiologist and Drew University research fellow, and Satoshi Omura, Ph.D., a Japanese biochemist, won the 2015 Nobel Prize in Physiology or Medicine for their research on the drug.

Other key COVID-19-related cases challenging the federal government are currently before the 5th Circuit, including the Missouri et al. v. Biden et al. and Kennedy et al. v. Biden et al. censorship cases. In July, the two cases were consolidated, while the 5th Circuit heard oral arguments in Missouri et al. v. Biden et al. last month.

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Michael Nevradakis, Ph.D.

Michael Nevradakis, Ph.D., based in Athens, Greece, is a senior reporter for The Defender and part of the rotation of hosts for CHD.TV's "Good Morning CHD."

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64 Comments

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Best Newest Oldest

holisticpoet 6 days ago edited

The sad thing about this case is that the real injustices are not even addressed. The big reason that Ivermectin was not allowed to be used was because, if there is a treatment for Covid19 then the vaccine could not be given EUA status. This was a pharmaceutical industry hit job against anything that would successfully treat Covid19.

In my opinion, the whole establishment that promoted the use of lethal remedies like Remdesivir and intubation, and discouraged the use of life saving drugs such as Ivermectin and Hydroxychloroquine, should not only be sued for monetary damages, pain and suffering, but should also be charged with murder. Then these agencies that are convicted of this need to be disbanded. We all know that they are controlled by the pharmaceutical companies.

49 0 Reply • Share ›

Laura Pieters → holisticpoet 6 days ago

They are all mass murderers no matter how you look at it!

13 0 Reply • Share ›

carlo151 → Laura Pieters 5 days ago

But we are living because of the vaccine. So how do you prove it Einstein?

0 6 Reply • Share ›

brbg → carlo151 5 days ago

The DNA altering drug, called a "vaccine," has been proven to be neither safe nor effective. It has seriously compromised the immune system of those who were so easily led to accept it.

8 0 Reply • Share ›

r2bzjudge → carlo151 5 days ago

In the Pfizer trial, the Covid shot failed end point. One more person died in the vax group, than the control group. Also, the Absolute Risk Reduction of the mRNA shots was only about 1% according to the trial data. The claim has been that the vax saved millions of lives, but that has never been proven by the CDC.

Remdesivir is a dangerous drug that failed on safety in Ebola testing. Never should have been used on hospitalized Covid patients. It was of no benefit to the patient. It actually caused harm to some patients, ultimately resulting in their death.

1 0 Reply • Share ›

Peter van der Stam → r2bzjudge 2 days ago edited

Good reason for Gates to experiment in African countries. Do they need it bribery??

0 0 Reply • Share ›

Peter van der Stam → carlo151 2 days ago

Except the ones who died shorty after the jab or booster. Explain that please!!

0 0 Reply • Share ›

Boopjr → holisticpoet 6 days ago

Exactly, I completely agree. I pray we see some civil law suits flying everywhere

12 0 Reply • Share ›

Caroline Cary Davidson → Boopjr 5 days ago

I do believe that the PREP act precludes any suit by patients. it made every hospital & practitioner legally exempt from liability. that's why they killed and maimed with such impunity.

7 0 Reply • Share ›

Stuff Happens → Caroline Cary Davidson 5 days ago

Should be able to claim extraordinary malfeasance via misuse of the law and sue them anyway.

1 0 Reply • Share ›

carlo151 → Caroline Cary Davidson 5 days ago

The vaccine did cause heart muscle problems with young who were in teir late teens or early twenties. However that same age group had twice the number of heart issues if they were unvaccinated and caught Covid. Covid attacked the heart also.

0 4 Reply • Share ›

Dana Wilkes → carlo151 5 days ago

The death rates on people who were playing sports (all around the World), went through the roof after the vaccines were given. There is no such thing as mild myocarditis. Heart injury is permanent.

9 0 Reply • Share ›

r2bzjudge → carlo151 5 days ago

Never heard of Myocarditis until after the vax came out. Myocarditis was not an issue in 2020, before the vax. The people winding up in the hospital in 2021, were vaxxed.

6 0 Reply • Share ›

Peter van der Stam → carlo151 2 days ago

Sorry , You are wrong again.
Did you prove this fact or took it as being true from Big Pharma who spread a lot of Mis information.

1 0 Reply • Share ›

Miles → carlo151 2 days ago

And where is your cited evidence for your bogus claim?

0 0 Reply • Share ›

L P → holisticpoet 6 days ago

I kept thinking that point would be mentioned, but nowhere. You're right, that's the real reason Ivermectin and other preventive/early treatments were suppressed, and the fraud hasn't been addressed yet and needs to be. I agree with everything you said 100%, we need full accountability and justice for all crimes, including genocide.

8 0 Reply • Share ›

colram → holisticpoet 6 days ago

I wholeheartedly share your opinion.

3 0 Reply • Share ›

Stuff Happens → holisticpoet 5 days ago

Agree. 100%

1 0 Reply • Share ›

carlo151 → holisticpoet 5 days ago

Could be, but highly unlikely.
The most logical reason is Ivermectin does not work. As we know, people, many people, can survive Covid. But Ivermectin had nothing to do with it.
The highest percentage of those that caught Covid and lived were those who were vaccinated starting in 2021.

The numbers are there. Compare death rates in anti-vaxx Florida #maga crowd with those who listen to their doctors and got vaccinated in a state like Maine that has plenty of elderly people.

0 8 Reply • Share ›

holisticpoet → carlo151 5 days ago

I don't understand how you can be so misinformed. The state of Pradesh India gave Ivermectin prophylactically to all 240 million of its people and had no new cases of Covid19. As for the rest of your statements which are unproven or outright lies, they make me wonder what financial stake you have to mislead readers?

10 0 Reply • Share ›

Stuff Happens → holisticpoet 5 days ago

In this circumstance there are two kinds of people. 1) The perpetually ignorant. 2) Those who support all covid mandates b/c they support authoritarianism. Every mass murderer in history had millions of supporters from both camps. That's how they flourished.

1 0 Reply • Share ›

r2bzjudge → carlo151 5 days ago

99 studies/trials say Ivermectin works just fine against Covid. Ralph Loriga sued hospitals on behalf of 80 dying Covid patients . Won and lost 40 each. 38 of the 40 who received Ivermectin, survived. 38 of the 40 denied Ivermectin, died. Yes, Ivermectin works.

6 0 Reply • Share ›

Stephen Simac → carlo151 5 days ago

The better comparison would be Florida vs California or New York state-both population size and demographics. No statistical difference despite diametrically opposed "public health guidance" around masking, lockdowns and social isolation. Vaccination rates were similar as both Trump and DeSantis were pro-vaxx.

2 0 Reply • Share ›

Phil 6 days ago

FDA/CDC/NIH must be held accountable for the deaths of thousands who could have been saved using HCL and IVM. They should also be held accountable for the thousands who have died and suffered heart damage from the untested mRNA gene therapy.

35 0 Reply • Share ›

GarySummers → Phil 6 days ago

I Pray they are all held Accountable!
Wife almost Died Twice from 'Blood Clots' Pfizer Jab!

A preprint paper published Monday criticized Pfizer's shady practices and procedures from its COVID-19 jab clinical trials.

The paper, titled "Forensic Analysis of the 38 Subject Deaths in the 6-Month Interim Report of the Pfizer/BioNTech BNT162b2 mRNA Vaccine Clinical Trial," is a "forensic analysis of the 38 trial subjects who died between July 27, 2020, the start of Phase 2/3 of the clinical trial, and March 13, 2021, the data end date of their 6-Month Interim Report."

The researchers stated, "the analysis reported here is unique in that it is the first study of the original data from the Pfizer/BioNTech BNT162b2 mRNA vaccine clinical trial (CA4591001) to be carried out by a group unaffiliated with the trial sponsor."
https://100percentfedup.com...

14 0 Reply • Share ›

tag → GarySummers 6 days ago

I hope your wife is now doing OK. This is a tragic thing on such a large scale it is hard for me to digest it. Not the country I grew up in anymore.

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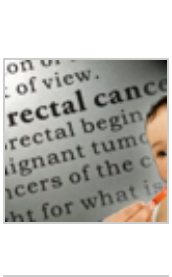

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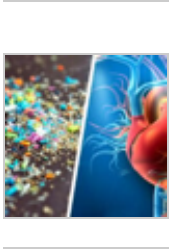

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3 0 Reply • Share ›

Boopjr → GarySummers
6 days ago

Exactly, that alone should allow people to sue Pfizer. If they were aware of this harm and still unleashed this shot without warning, then they can be sued. This makes me so mad. They knew the harm it could cause and still do and are still trying to push the poison.

3 0 Reply • Share ›

GarySummers → Phil
6 days ago

"Fauci Would "Prescribe Chloroquine" to Patient Suffering From COVID-19"
https://townhall.com/column...

5 0 Reply • Share ›

GarySummers
6 days ago

*

see more

19 0 Reply • Share ›

tag → GarySummers
6 days ago

And know if you are eating it MUST stay away! LOL!

0 0 Reply • Share ›

GarySummers
6 days ago

EXCLUSIVE 'Great News'!
Sharing Is Caring

"Re: FDA ruled against by a Federal court over Anti-Ivermectin messaging"
'This was an enormously significant ruling.'!

Viva Frei and 'CHD Attorney Robert Barnes'. #28 MIN MARK!
https://rumble.com/v3ee55g-...

Barnes breakdown on this, the FDA is not allowed to medical advice not even a tweet. They're really there to ensure things are properly labeled and legal things are met. licensing.

Not doctors. And this law suit brought up that due to their heavy handed "advice" they were fired, they had their licenses revoked by boards.

"None of them are allowed to give advice or interfere with Doctors."!

And this apparently extends to many many other things and to the shot itself and to a number of people; FDA, FAUCI, SOCIAL MEDIA CENSORSHIP and Fact CHecks and advice that had children and adults die and be maimed for life. Millions.

*He said the 'lawsuits are going to begin *suing everyone* involved', giving advice. news? FAUCI was mentioned as a target!*

18 0 Reply • Share ›

Char → GarySummers
5 days ago

But will they ever be held accountable personally?

2 0 Reply • Share ›

mcwinaz
6 days ago

So does this case now go back to the lower court to ultimately decide what happens to FDA? Hopefully the 3 doctors are asking for massive $$ payouts for what's been done to them because, beyond that, the FDA will probably yawn at any final verdict in this..

14 0 Reply • Share ›

Caroline Cary Davidson → mcwinaz
5 days ago

I am looking at it as kind of a legal test balloon, to get a legal interpretation of the FDA authority and standing of others to sue. I read the entire document. three point were tried; only the last one (question of authority) was found as cause to reverse the original dismissal.

2 0 Reply • Share ›

Char
5 days ago

We are left with a terrible nagging fear: Can we EVER trust doctors & their immunizations, again?

9 0 Reply • Share ›

Jennifo → Char
5 days ago

Nope. Kinda stopped years ago to be honest.

5 0 Reply • Share ›

Caroline Cary Davidson → Jennifo
5 days ago

me too

1 0 Reply • Share ›

Caroline Cary Davidson → Char
5 days ago

that would be a HARD NO.

4 0 Reply • Share ›

Fred Secret → Char
5 days ago

Vaccine Injury Compensation Program has just passed $5 BILLION in payouts to vax injured people since its inception in 1989. So what do you think?
https://www.hrsa.gov/sites/...

3 0 Reply • Share ›

Fisher153 → Fred Secret
5 days ago

how much to covid shot victims??? about $8000. worthless taxpayer-funded cover-up program.

https://rwmalonemd.substack...

0 0 Reply • Share ›

tag
6 days ago

I don't know, i kind of thank them. When they tell me something isn't good for me it is obvious to me it is something I need to consider. And I did. Kept me out of one of those pay to play death chambers, AKA hospital. Thanks FDA and keep your "recommendations" coming so I can save my own life. And pay attention Bill, Anthony and Joe. I feel exactly the same about what your mouths spout.

7 0 Reply • Share ›

Jennifo → tag
5 days ago

agree! If 'they' are telling you to do it/get it, do the opposite!

5 0 Reply • Share ›

Keith
5 days ago

I asked my doctor "If I get infected by this Chinese Bio-Weapon designed by Fauci, paid for with American Tax Dollars and released by the Chinese Communist Party could and would he supply these two drugs for what was acknowledged as a cure by thousands of Americans?" He said NO. I got a different Doctor.

6 0 Reply • Share ›

Adrianne42
5 days ago

I just read an article https://brightworkresearch.... saying ivermectin fights cancer, auto-immune diseases, nerve damage, neuropathy, and more. This is off-patent, cheap, and probably works by boosting your immune system, so it does no damage to healthy tissue, side effects are shallow, and it could be used as a preventative. The entire medical industry would have been destroyed if word had gotten out. They had to block IVM use or lose their money pot. The medical industry knows that IVM fights cancer
https://www.ncbi.nim.nih.go... Ivermectin, a potential anticancer drug of course there has been inadequate research - blah, blah, blah

6 0 Reply • Share ›

A. Miller
6 days ago

Would love to know what everyone believes to be a fair punishment for this indiscretion... Personally, I think this is a capital crime and mass murder.

6 0 Reply • Share ›

Caroline Cary Davidson → A. Miller
5 days ago

the only thing this reversal will do is let the suit (civil, not criminal) move forward on the basis of FDA acting outside its authority

0 0 Reply • Share ›

Gary Brown
5 days ago

Instead, the Bill Gates corrupted medical mafia went this way.

September 6, 2023 Turbo Cancer: Teachers Are Being Decimated by Aggressive and Metastatic Cancers After COVID-19 mRNA Vaccine Mandates By Dr. William Makis

Aug. 21, 2023 – Loveland, CO – Emma who is a young teacher and soccer coach was attending a game, when she received a soccer ball kick to the head, had a seizure and was found to have a brain tumor.

https://www.globalresearch....

see more

4 0 Reply • Share ›

Anna Dulin
5 days ago

The how did Biden have the authority to "endorse , advise" and order ("get your vaccine"). He is not a physician! He should be sued too! I had to quit my job because of his "advise"!

4 0 Reply • Share ›

RubyTwoThree
6 days ago

I met Dr. Marik at a lecture once, he is a true gem of a man and human being. I want him to be compensated for his pain and suffering, the lies, and abuse they did to him, and his patients by taking him away from them.

4 0 Reply • Share ›

Beatrice Zirth
6 days ago edited

My doctor prescribed 5 days of ivermectin for my wife and I. Publix pharmacy has not 1 but 2 exclamation point warningst that say "Warning" The FDA has not aproved the use of ivermectin for treatment of Covid19 in humans". So what, right? So I try to fill it and they wanted $650 for a 5 day supply for my wife and I. So they are going to do what they want regardless of any court rulings.

4 0 Reply • Share ›

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